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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,329

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MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

NOTIFICATION DATE

DELIVERY MODE

12/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

EOfficeSD@mofo.com

Office Action Summary	Application No. 10/566,329	Applicant(s) XIAN ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-30 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-30 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10, 11/10</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 22 November 2010 in which claims 1, 4-5, 8, 12, 19, 25, 28 and 55 were amended and claim 3 was canceled. The amendments add the enclosure of canceled Claim 3 to independent Claims 1 and 55. The amendments further define the enclosure as "attached to" the microarray chip. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 20 August 2010 are withdrawn in view of the amendments.

Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the amendment, are discussed.

Claims 1-2, 4-30 and 55 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 4-30 and 55 rejected under 35 U.S.C. 102(e) as being anticipated by Xing et al (U.S. Patent No. 7,767,438, filed 28 March 2003).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding Claims 1-2, 4-30 and 55, all the element of the instant claims are taught and/or claimed in the '438 patent. The patent claims differ from the instantly claimed device in that the patent claims are further drawn to a microarray chip having projections in addition to the instantly claimed cover having projections. However, the additional projections of the patent are encompassed by the open claim language "comprising" of the instant claims. Therefore, the '438 patent anticipates the device as instantly claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2, 4-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webb et al (U.S. Patent No. 7,332,328, filed 6 September 2002) in view of MacBeath et

al (U.S. Patent No. 7,063,979, filed 13 June 2002) or Oldenburg (U.S. Patent No. 7,025,120, filed 31 January 2003).

Regarding Claim 1, Webb teaches a microarray device having a plurality of microarray areas (6) and a cover (12) having a plurality of projections (3) wherein a plurality of microarray reaction spaces are formed between the chip and projections and wherein the volumes of the reaction spaces are identical and controllable by the height of the cover and projections (Column 3, lines 4-23, Column 12, line 60-Column 13, line 5 and Fig. 3A/B). It is noted that Webb teaches that microarrays are formed on the projections and/or bottom of wells (Column 3, lines 13-15). Webb further teaches that a pre-formed seal is placed at the base of each column and/or the opening of each well and/or around the periphery of the multi-well plate (Column 9, line 66-Column 10, line 17). Webb illustrates the pre-formed seal (i.e. annulus (26/26a)) in figure 5. Webb further teaches the annulus prevents cross-contamination, minimizes evaporation and provides micro-environments and individual temperature control (Column 10, lines 11-17). The sealing enclosure of Webb appears to only differ from that claimed in that the reference teaches multiple seals forming the enclosure. That is, Webb uses a seal at the base of each column and/or the opening of each well and/or around the periphery of the multi-well plate (Column 9, line 66-Column 10, line 17).

However, single-piece construction of enclosures for a plurality of microarrays was well known in the art at the time the invention was made as taught by MacBeath.

It is further noted that the courts have stated “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter

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of obvious engineering choice” (see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) MPEP § 2144.04).

Therefore using a one-piece construction for multiple seals of Webb would have merely been a matter of obvious engineering choice especially based on the well known use of single-constructed enclosures as taught by MacBeath.

Alternatively, Webb teaches the device provides micro-environments and individual temperature control (Column 10, lines 11-17). Oldenburg teaches a device comprising a plurality of reaction spaces (Fig 1) and a cover having a plurality of projections (Fig. 2) wherein an enclosure (gasket 26) is attached to the reaction spaces and cover thereby providing individual temperature control of individual wells by application or removal of heat via the projections (Column 3, lines 11-30 and Column 4, lines 54-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cover and gasket of Oldenburg to the device of Webb. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing means for controlling temperature within each reaction area as desired by Webb (Column 10, lines 11-17).

Regarding Claim 2, Webb teaches the device wherein the chip is a glass slide (Example 2, Column 20, line 7).

Regarding Claim 4, Webb is silent regarding the thickness of the gasket. However, MacBeath teaches the gasket of 0.25-3mm (Column 8, lines 34-36) which is within the claimed range of 0.05 to 50mm.

Regarding Claim 5, Webb teaches the device wherein the gasket has a round or rectangular shape (Fig. 5). And MacBeath teaches the gasket is rectangular (Column 8, lines 1-22).

Regarding Claim 6, Webb teaches the device wherein the cover has a through hole (50) for fluid delivery (Column 12, lines 32-54).

Regarding Claim 7, Webb teaches the device wherein each projection has 1-6 through holes (Column 12, lines 49-54). The 96-well plate having 1-6 through holes is encompassed by the claimed range of 1 to 2,500.

Regarding Claim 8, Webb teaches the projections have 1-6 through holes. The claim defines identical or different number of projections and through hole. The instantly claimed identical or different number encompasses any number of through holes per projection. Therefore, Webb anticipates the instantly claimed device.

Regarding Claims 9-10, Webb teaches the through hole has a circular shape i.e. cross-sectional diameter of 500 μm (Column 12, lines 45-46).

Regarding Claim 11, Webb teaches the device wherein the number of projections and/or microarray areas are between 2 and 2500 (i.e. a standard 96, 384 or 1536-well plate microtiter plate, Column 8, lines 30-43).

Regarding Claim 12, Webb teaches the device wherein the number of projections and microarray areas are the same (Fig. 3 and 6). The claim defines identical or different number of projections and microarray areas. The instantly claimed identical or different number encompasses any number of through holes per projection. Therefore, Webb anticipates the instantly claimed device.

Regarding Claim 13, Webb teaches the device wherein the projections and microarray areas have the same shapes i.e. the projections have the same shape and the microarray areas formed by the microtiter plate have the same shape (Column 8, lines 30-60, Column 10, lines 18-54 and Fig. 3 & 6).

Regarding Claim 14, Webb teaches a gap area formed between the cover and substrate comprising the projections and microarray reaction areas wherein the gap is 175 μm (Example 2, Column 20, lines 4-10). Hence, the projections are within the claimed range of 0.01 to 50mm.

Regarding Claim 15, Webb teaches the device wherein the projections have a shape selected from square and circle (Fig. 2).

Regarding Claim 16, Webb teaches the device wherein the surface of the projections has an area of 10-250 microns (Column 14, lines 63-65) which is within the claimed range of 0.01 to 600 mm^2

Regarding Claim 17, Webb teaches the device wherein a gap comprising the projections and microarray reaction area is formed between the cover and substrate wherein the gap is 175 μm (Example 2, Column 20, lines 4-10) which is within the claimed range of 0.001 to 1mm.

Regarding Claim 18, Webb teaches the device wherein the reaction volume is 9 (Example 2, Table 4) which is within the claimed range of 0.01 to 600 mm^2 .

Regarding Claim 19, Webb teaches the device wherein the substrate comprises glass, metal or plastic (Column 14, lines 33-55).

Regarding Claims 20-21, Webb teaches the device wherein the cover comprises plastic (Column 14, lines 33-36). The reference further teaches injection molding (Column 13, lines 19-21). However, it is noted that, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

Regarding Claim 22, Webb teaches the cover comprises polypropylene or polystyrene (Column 13, lines 54-58).

Regarding Claims 23-24, Webb teaches the device wherein the cover comprises glass (Column 13, lines 13-63). The reference further teaches that the projections are provided by sliced-array techniques (Column 9, lines 49-65). However, absent evidence to the contrary, the claimed process for making the cover does distinguish the cover made by another method.

Regarding Claims 25-29, Webb teaches the device wherein the microarray reaction areas separated by annulus (Column 9, line 66-Column 10, line 17). but the reference is silent regarding double-sided tape.

However, silicone/rubber chambers for forming reaction chambers were known to use adhesive tape (e.g. double-sided and/or compressable material treated for adhesion) for forming water-tight seals as taught by MacBeath (Column 8, lines 55-67 and Column 17, lines 18-50). MacBeath teaches the device wherein the treated gaskets provide the chambers with a watertight seal between the gasket and the microarray thereby preventing cross-contamination between the wells/chambers (Column 6, line 53-Column 7, line 20). It would have been obvious to one of ordinary

skill in the art at the time the claimed invention was made to modify the silicone chamber of Webb by adding the double-sided tape adhesive of MacBeath. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of providing a water-tight seal between the wells/chamber thereby preventing cross-contamination as taught by MacBeath (Column 6, lines 53-67).

Claims 26 and 28 define methods for making the enclosure by stamping. However, as noted above, the courts have stated that a process for making a device does not define the device over a prior art device made by another method. Therefore the instantly claimed stamping does not patentably distinguish the device.

Regarding Claim 30, Webb teaches the device wherein a reactant (i.e. probe) is immobilized in the array area (Column 3, lines 4-23).

Regarding Claim 55, Webb teaches a microarray device having a microarray area (6) and a cover (12) having a projection (3) wherein a microarray reaction space is formed between the chip and projection and wherein the volume of the reaction space is controllable by the height of the cover and projection (Column 3, lines 4-23, Column 12, line 60-Column 13, line 5 and Fig. 3A/B).

Webb further teaches that a pre-formed seal is placed at the base of each column and/or the opening of each well and/or around the periphery of the multi-well plate (Column 9, line 66-Column 10, line 17). Webb illustrates the pre-formed seal (i.e. annulus (26/26a)) in figure 5. Webb further teaches the annulus prevents cross-contamination, minimizes evaporation and provides micro-environments and individual

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temperature control (Column 10, lines 11-17). The sealing enclosure of Webb appears to only differ from that claimed in that the reference teaches multiple seals forming the enclosure. That is, Webb uses a seal at the base of each column and/or the opening of each well and/or around the periphery of the multi-well plate (Column 9, line 66-Column 10, line 17).

However, single-piece construction of enclosures for a plurality of microarrays was well known in the art at the time the invention was made as taught by MacBeath.

It is further noted that the courts have stated “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice” (see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) MPEP § 2144.04).

Therefore using a one-piece construction for multiple seals of Webb would have merely been a matter of obvious engineering choice especially based on the well known use of single-constructed enclosures as taught by MacBeath.

Alternatively, Webb teaches the device provides micro-environments and individual temperature control (Column 10, lines 11-17). Oldenburg teaches a device comprising a plurality of reaction spaces (Fig 1) and a cover having a plurality of projections (Fig. 2) wherein an enclosure (gasket 26) is attached to the reaction spaces and cover thereby providing individual temperature control of individual wells by application or removal of heat via the projections (Column 3, lines 11-30 and Column 4, lines 54-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the cover and gasket of Oldenburg to the

device of Webb. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing means for controlling temperature within each reaction area as desired by Webb (Column 10, lines 11-17).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-30 and 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,767,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a device comprising a cover having projections and a microarray chip wherein microarray areas are formed between the projections and chip. The claim sets differ in that the patent claims are further drawn to projections on the microarray chip in addition to the instantly claimed cover having projections. However, the additional projections of the patent are encompassed by the open claim language "comprising" of the instant claims. Therefore, the instantly claimed device is not patentably distinct from the '438 patent.

Response to Arguments

8. Applicant argues that Xing differs from the instantly claimed device because the reference does not teach the newly defined enclosure.

The argument is not found persuasive because Xing teaches a device comprising, among other elements, "a supporting structure" and "a positioning structure". The patent defines the structures at Column 12, lines 7-10 as follows:

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The supporting structure (3) and the positioning structure (4) can be used to control the relative positions between the plurality of projections on the microarray chip (1) and the cover (2) to form the numerous reaction spaces (8) with controllable thickness or volume. (emphasis added)

Therefore the patent defines the claimed structures as forming reaction spaces as instantly claimed.

Applicant argues that Webb does not teach an enclosure attached to the microarray chip to form a plurality of microarray areas.

The argument has been considered but is not found persuasive. The newly defined enclosure, attached to the chip, forms a plurality of reaction areas. As noted above, Webb teaches seals (annulus 26/26a) forming micro-environments. Therefore, the enclosure of Webb is very similar to that claimed. Furthermore, gaskets forming a plurality of micro-environments were well known in the art as taught by MacBeath and Oldenburg. Therefore, it is the opinion of the examiner that the newly claimed enclosure is an obvious modification of the prior art as discussed above.

Applicant argues that one of ordinary skill in the art would not have been motivated to combine the teachings of MacBeath with those of Webb because doing so would have rendered the intended purpose of Webb unsatisfactory.

The argument has been considered but is not found persuasive. Applicant has not provided any reasoning for the asserted unsatisfactory modification. Furthermore, Webb is specifically interested in sealing individual wells/microarray reaction area.

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Webb only appears to differ from the instantly claimed enclosure is that Webb seals each well while the instantly claimed enclosure seals a plurality of wells. However, as noted above, the courts have stated “that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.”. Hence, making the multiple seals of Webb would have been obvious. Furthermore, one piece construction of multi-well seals were well known and routinely used in the art as taught by MacBeath and Oldenburg.

It is maintained that the combination of Webb and MacBeath is proper and that the instantly claimed device is an obvious combination of the prior art.

Regarding the non-statutory double patenting rejection, Applicant argues that the patent does not teach the newly claimed attached enclosure forming a plurality of reaction areas. The argument is not found persuasive. The patent claims are drawn to, among other elements, “a supporting structure” and “a positioning structure”. The patent specification defines the structures at Column 12, lines 7-10 as follows:

The supporting structure (3) and the positioning structure (4) can be used to control the relative positions between the plurality of projections on the microarray chip (1) and the cover (2) to form the numerous reaction spaces (8) with controllable thickness or volume. (emphasis added)

Therefore the patent defines the claimed structures as forming reaction spaces as instantly claimed.

It is maintained that the instantly claimed device is not patentably distinct from the patent.

Conclusion

9. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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